REMARKS

Claims 1-37 have been rejected and remain pending. In addition, claim 1 has been amended to add a common after the word "fiber." No new matter has been added.

In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 1-37.

Examiner Interview

Applicants' agent thanks Examiner Naff for the courtesy of the telephonic interview on April 8, 2004. The substance of this telephonic interview involved the rejections and arguments presented herein.

Rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 1-7, 9-20, and 24-34 under 35 U.S.C. § 103(a) as being unpatentable over Ducheyne (U.S. Patent No. 5,030,233) in view of Davidson (U.S. Patent No. 5,690,670) and Vacanti *et al.* (U.S. Patent No. 5,567,612). Specifically, the Examiner stated that the Ducheyne reference discloses a porous metal material for surgical implantation having a pore size of at least 150 micrometers. The Examiner also stated that the material shown in Figure 1 of the Ducheyne reference is non-woven. In addition, the Examiner stated that (1) the Davidson reference discloses stents or vascular grafts fabricated from a metal alloy, and (2) the Vacanti *et al.* reference discloses an implant that can contain cells. In response to Applicants' previous submission, the Examiner alleged that "it would have been obvious that the implant of Ducheyne can be used as a stent or vascular graft when the device is shaped for this use." The Examiner also concluded that "providing the device with cells and extracellular matrix protein would have been obvious when the functions of these components as [sic, are] disclosed by Vacanti *et al.*"

Applicants respectfully disagree and submit that this rejection is improper for several reasons. First, a person having ordinary skill in the art of vascular implants would not have reasonably been expected or motivated to look to fields relating to bone implants or artificial urological structures, since bone implants and artificial urological structures are vastly different from vascular implants. For example, the bone implants disclosed in the Ducheyne reference are designed to be pressed or packed into a bone in need of repair. The artificial urological

structures disclosed in the Vacanti *et al.* reference are biodegradable matrices containing urothelial cells that are designed to replace or repair kidneys, bladders, or other urological structures. Vascular implants are completely unrelated to such bone implants and artificial urological structures.

During the Examiner's interview conducted April 8, 2004, the Examiner appeared to argue that the cited references are from an art analogous to the art of the claimed invention in that they all relate to implants. Applicants respectfully submit that hundreds of different implants have been described over the years (e.g., joint pins, artificial hearts, artificial discs, breast implants, and dermal fillers) that can fall into non-analogous arts. Thus, the fact that an item is called an implant does not necessarily mean that that item is analogous to another item called an implant. In *In re Oetiker*, the United States Patent and Trademark Office Board of Patent Appeals and Interferences reasoned that all hooking problems are analogous. See, *In re Oetiker*, 977 F.2d 1443, 1446-1447 (Fed. Cir. 1992). The Federal Circuit, however, held that the Board did not show that a person of ordinary skill, seeking to solve a problem of fastening a hose clamp, would reasonably be expected or motivated to look to fasteners for garments. In other words, not all hooking problems are analogous. Given the above and the lack of evidence demonstrating that a person of ordinary skill in the art of vascular implants would have reasonably been expected or motivated to look to the bone implants of the Ducheyne reference or the artificial urological structures of the Vacanti *et al.* reference, it is clear that this rejection under 35 U.S.C. 103(a) should be withdrawn.

Second, even assuming for the sake of argument that the cited references can be combined as the Examiner contends, the cited references do not teach or suggest that a person having ordinary skill in the art should make or use the presently claimed implantable medical devices or non-woven frameworks. In fact, at no point does the combination of cited references teach or suggest that a person having ordinary skill in the art should make or use any device that contains cells and is implantable within the vascular system of a mammal. Moreover, a person having ordinary skill in the art reading the cited references would not have been motivated to provide the metal fiber implant of the Ducheyne reference with cells. This is especially true given the Ducheyne reference's teaching that the implanted material must meet certain criteria including, for example, stability for autoclaving. See, column 5, lines 20-25 and column 5, lines

38-42. Applicants' respectfully submit that implantable medical devices comprising cells are not stable for autoclaving. Thus, a person having ordinary skill in the art appreciating the requirements set forth in the Ducheyne reference would not have been motivated to modify the materials of the Ducheyne reference as alleged by the Examiner.

The Examiner stated that "it would have been obvious that the implant of Ducheyne can be used as a stent or vascular graft when the device is shaped for this use." The issue, however, is that this rationale is the very "suggestion" that is missing from the cited art, and is conclusory. At no point does the Ducheyne reference disclose an implant shaped for use as a stent or vascular graft. In fact, the Ducheyne reference never mentions shaping a bone implant into a stent or vascular graft. The patent law is clear in that there must be some reason, suggestion, or motivation found in the prior art to make the claimed invention. In particular, proper analysis under § 103 requires consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition, and (2) whether the prior art would also have revealed that in so making, those of ordinary skill would have a reasonable expectation of success. See, *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). The combination of cited references fails to provide any suggestion that a person having ordinary skill in the art should modify a bone implant of the Ducheyne reference to make the presently claimed inventions. Absent such motivation, the present claims are not obvious.

The Examiner also stated that "providing the device with cells and extracellular matrix protein would have been obvious when the functions of these components as [sic, are] disclosed by Vacanti *et al.*" Thus, the Examiner appears to imply that knowing the functions of the cells and extracellular matrix proteins disclosed in the Vacanti *et al.* reference somehow motivates a person having ordinary skill in the art to make, for example, a vascular implant containing cells. This is not correct. The Vacanti *et al.* reference discloses biodegradable matrices containing urothelial cells that are designed to replace or repair kidneys, bladders, or other urological structures. Knowing that urothelial cells on a biodegradable matrix can function to replace or repair a kidney or bladder falls far short of suggesting that a person having ordinary skill in the art should make, for example, a vascular implant containing a non-woven framework and cells. Thus, the cited references do not render the present claims obvious.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 1-7, 9-20, and 24-34 under 35 U.S.C. § 103(a).

The Examiner also rejected claims 8, 21-23, and 35-37 under 35 U.S.C. § 103(a) as being unpatentable over Ducheyne (U.S. Patent No. 5,030,233) in view of Davidson (U.S. Patent No. 5,690,670) and Vacanti *et al.* (U.S. Patent No. 5,567,612) as applied to claims 1-7, 9-20, and 24-34 above, and further in view of Ferrara *et al.* (U.S. Patent No. 6,455,283).

Applicants respectfully disagree. As explained above, the combination of the Ducheyne, Davidson, and Vacanti *et al.* references does not render claims 1-7, 9-20, and 24-34 obvious. The Ferrara *et al.* reference does not cure the deficiencies of the Ducheyne, Davidson, and Vacanti *et al.* references. In fact, the Ferrara *et al.* reference discloses nucleic acids encoding vascular endothelial growth factor-E. At no point does the Ferrara *et al.* reference teach or suggest that a person having ordinary skill in the art should modify the materials of the Ducheyne reference to obtain the presently claimed inventions. Thus, the cited references do not render the present claims obvious.

In light of the above, Applicants respectfully request withdrawal of the rejections of claims 8, 21-23, and 35-37 under 35 U.S.C. § 103(a).

CONCLUSION

Applicants submit that claims 1-37 are in condition for allowance, which action is requested. The Examiner is invited to call the undersigned agent at the telephone number below if such will advance prosecution of this application. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: April 16, 2004

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